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IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, ASTRAZENECA AB, KUDOS PHARMACEUTICALS LIMITED, THE UNIVERSITY OF SHEFFIELD, and MSD INTERNATIONAL BUSINESS GMBH,

Plaintiffs,

v.

NATCO PHARMA LIMITED, NATCO PHARMA INC., SANDOZ INC., CIPLA LIMITED, CIPLA USA, INC., ZYDUS PHARMACEUTICALS (USA) INC. and ZYDUS LIFESCIENCES LIMITED

Defendants.

Civil Action No. 3:23-796 (RK) (TJB)
(Consolidated)

ANSWER, SEPARATE DEFENSES, AND COUNTERCLAIMS

Document Electronically Filed

Defendants Cipla USA, Inc. and Cipla Limited (collectively, "Cipla" or "Defendants"), by and through their attorneys, respond to each of the numbered paragraphs in the Complaint by Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, AstraZeneca AB, KuDOS Pharmaceuticals Limited, and MSD International Business GmbH (collectively, "Plaintiffs") as follows[1]:

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, which arises out of the submission by Cipla of an Abbreviated New Drug Application ("ANDA") to the United States Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a generic version of LYNPARZA® (olaparib) tablets, 100 mg and 150 mg, prior to the expiration of U.S. Patent No. 12,144,810 ("the '810 patent").

ANSWER: Cipla admits that Plaintiffs' Complaint purports to be based upon the patent laws of the United States, 35 U.S.C. § 100 *et seq*. Cipla admits that Cipla Limited prepared and submitted Cipla's Abbreviated New Drug Application ("ANDA") No. 219410 ("Cipla's ANDA") to the U.S. Food and Drug Administration ("FDA") pursuant to 21 U.S.C. § 355(j), and that Cipla's ANDA seeks approval from the FDA to engage in the commercial manufacture, use, and/or sale, of the product described in Cipla's ANDA ("Cipla's ANDA Product") prior to the expiration of U.S. Patent No. 12,144,810 (the "'810 patent"). Cipla denies the remaining allegations in paragraph 1.

2. Cipla notified Plaintiffs by letter dated May 21, 2024 ("Cipla's Notice Letter") that it had submitted to FDA ANDA No. 219410 ("Cipla's ANDA"), seeking approval from FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic olaparib tablets, 100 mg and 150 mg, ("Cipla's ANDA Product") prior to the expiration of U.S.

[1] This Answer reproduces the headings of the Complaint for convenience only. This reproduction of the headings should not be construed as an admission of any of the allegations in the Complaint. Pursuant to Federal Rule of Civil Procedure 8(b)(3), Defendants deny all allegations in the Complaint except those specifically admitted.

Patent Nos. 8,859,562 ("the '562 patent"), 8,475,842 ("the '842 patent"), and 11,633,396 ("the '396 patent").

ANSWER: Cipla admits that Cipla notified Plaintiffs by letter dated May 21, 2024 ("Cipla's May 2024 Notice Letter") that Cipla had submitted Cipla's ANDA seeking approval from the FDA to engage in the commercial manufacture, use, and/or sale of Cipla's ANDA Product, prior to the expiration of the U.S. Patent No. 8,859,562 (the "'562 patent"), U.S. Patent No. 8,475,842 (the "'842 patent"), and U.S. Patent No. 11,633,396 (the "'396 patent"). Cipla denies any remaining allegations of paragraph 2.

3. Plaintiffs filed suit against Cipla in this District, asserting that Cipla's ANDA infringes the '562 patent, the '842 patent, the '396 patent, U.S. Patent No. 11,970,530 ("the '530 patent"), and U.S. Patent No. 11,975,001 ("the '001 patent"). See *AstraZeneca Pharms. L.P. v. Cipla Limited*, Civ. No. 24-7346, Dkt. No. 1. That suit is currently pending in this District. The parties subsequently stipulated to the dismissal without prejudice of Plaintiffs' infringement claims based on the '842 patent, the '396 patent, and the '530 patent. *AstraZeneca Pharms. L.P. v. Natco Pharma Ltd.*, Civ. No. 23-796, Dkt. No. 112. Plaintiffs then filed suit against Cipla asserting that Cipla's ANDA infringes U.S. Patent No. 12,048,695. *See AstraZeneca Pharms. v. Cipla Ltd.*, Civ. No. 24-8167, Dkt. No. 1. That case was consolidated, along with other litigation involving Plaintiffs' patent infringement claims relating to generic olaparib tablets. See *AstraZeneca Pharms. L.P. v. Natco Pharma Ltd.*, Civ. No. 23-796, Dkt. No. 108.

ANSWER: Cipla admits that Plaintiffs filed suit against Cipla in this District, asserting that Cipla's ANDA infringes the '562 patent; the '842 patent; the '396 patent; U.S. Patent No. 11,970,530 (the "'530 patent"); and U.S. Patent No. 11,975,001 (the "'001 patent"). *See AstraZeneca Pharms. L.P. v. Cipla Limited et al.*, Civ. No. 3:24-7346, Dkt. No. 1. Cipla further admits that *AstraZeneca Pharms. L.P. v. Cipla Limited et al.*, Civ. No. 24-7346 is currently pending in this District. Cipla admits that Plaintiffs filed, and the Court so ordered, a Notice of Voluntary Dismissal for all claims of the '530 patent, the '842 patent, and the '396 patent that were asserted against Cipla. *See AstraZeneca Pharms. L.P. v. Natco Pharma Ltd. et al.,* Civ. No. 3:23-796, Dkt. Nos. 112, 113. Cipla further responds that, on November 1, 2024, the Court entered a Consent Decree and Judgment of Non-Infringement regarding the '842 patent. *See AstraZeneca*

Pharms. L.P. v. Natco Pharma Ltd. et al., Civ. No. 3:23-796, Dkt. No. 147. Cipla admits that the Court entered a Stipulation and Proposed Order of Dismissal, dismissing, *inter alia*, Plaintiffs' infringement claims based on the '842 patent and the '396 patent. *See AstraZeneca Pharms. L.P. v. Natco Pharma Ltd. et al.,* Civ. No. 3:23-796, Dkt. No. 148. Cipla further admits that Plaintiffs filed suit in this District alleging that Cipla's ANDA infringes U.S. Patent No. 12,048,695 (the "'695 patent"). *AstraZeneca Pharms. v. Cipla Ltd.*, Civ. No. 3:24-8167, Dkt. No. 1. Cipla admits that case was consolidated into *AstraZeneca Pharms. L.P. v. Natco Pharma Ltd.*, Civ. No. 3:23-796. Cipla denies any remaining allegations of paragraph 3.

The Parties

4. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership organized and existing under the laws of the State of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803. AstraZeneca Pharmaceuticals LP is the holder of New Drug Application No. 208558 for the manufacture and sale of LYNPARZA® (olaparib) tablets.

ANSWER: Cipla admits that New Drug Application No. 208558 is approved by the FDA. Cipla states that the FDA's electronic *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") lists AstraZeneca Pharmaceuticals LP as the holder of New Drug Application No. 208558. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations in this paragraph and therefore denies them.

5. Plaintiff AstraZeneca UK Limited is a private company limited by shares organized and existing under the laws of England and Wales, whose registered office is at 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge CB2 0AA, United Kingdom.

ANSWER: Cipla lacks sufficient information or knowledge to admit or deny the allegations in this paragraph and therefore denies them.

6. Plaintiff AstraZeneca AB is a limited company organized and existing under the laws of Sweden, whose registered office is at SE-151 85, Södertälje, Sweden.

ANSWER: Cipla lacks sufficient information or knowledge to admit or deny the allegations in this paragraph and therefore denies them.

7. Plaintiff KuDOS Pharmaceuticals Limited is a private company limited by shares organized and existing under the laws of England and Wales, whose registered office is at 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge CB2 0AA, United Kingdom.

ANSWER: Cipla lacks sufficient information or knowledge to admit or deny the allegations in this paragraph and therefore denies them.

8. Plaintiff MSD International Business GmbH is a company with limited liability organized and existing under the laws of Switzerland, whose registered office is at Tribschenstrasse, 60, 6005 Lucerne, Switzerland.

ANSWER: Cipla lacks sufficient information or knowledge to admit or deny the allegations in this paragraph and therefore denies them.

9. On information and belief, Defendant Cipla Limited is a corporation organized under the laws of the Republic of India, with a place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai, Maharashtra 400013, India.

ANSWER: Cipla admits that Cipla Limited is a company organized under the laws of India, having a place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400013, India. Cipla denies any remaining allegations of paragraph 9.

10. On information and belief, Defendant Cipla USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business in Warren, New Jersey. On information and belief, Cipla USA, Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

ANSWER: Cipla admits that Cipla USA, Inc. is a company organized and existing under the laws of the State of Delaware, with its principal place of business in Warren, New Jersey. Cipla admits that Cipla USA, Inc. distributes pharmaceutical drug products, including generic drug products, for sale. Cipla denies the remaining allegations in paragraph 10.

11. On information and belief, Cipla USA, Inc. is a wholly owned subsidiary of Cipla Limited and is controlled by Cipla Limited.

ANSWER: Cipla admits that Cipla USA, Inc. is a wholly-owned subsidiary of InvaGen Pharmaceuticals, Inc., which is a wholly-owned subsidiary of Cipla (EU Limited), which is a wholly-owned subsidiary of Cipla Limited. Cipla denies any remaining allegations of paragraph 11.

12. On information and belief, Cipla Limited and Cipla USA, Inc. acted in concert to prepare and submit Cipla's ANDA to the FDA.

ANSWER: Paragraph 12 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla admits that Cipla Limited and Cipla USA, Inc. seek regulatory approval of pharmaceutical drug products, including generic products. Cipla denies the remaining allegations in paragraph 12.

13. On information and belief, Cipla Limited and Cipla USA, Inc. know and intend that upon approval of Cipla's ANDA, Cipla Limited will manufacture Cipla's ANDA Product and Cipla Limited and Cipla USA, Inc. will directly or indirectly import Cipla's ANDA Product into the United States and market, sell, and distribute Cipla's ANDA Product throughout the United States, including in New Jersey.

ANSWER: Cipla admits that Cipla Limited and Cipla USA, Inc. prepared and submitted Cipla's ANDA to FDA pursuant to 21 U.S.C. § 355(j), and that Cipla seeks approval from the FDA to engage in the commercial manufacture, use, and/or sale of Cipla's ANDA Product. Cipla will decide whether to market its product in the United States upon FDA approval. Cipla denies the remaining allegations in paragraph 13.

14. On information and belief, following any FDA approval of Cipla's ANDA, Cipla Limited and Cipla USA, Inc. will act in concert to distribute and sell Cipla's ANDA Product throughout the United States, including in New Jersey.

ANSWER: Paragraph 14 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 14

as phrased and affirmatively states that Cipla will decide whether to market its product in the United States upon FDA approval. Cipla denies any remaining allegations of paragraph 14.

Jurisdiction

15. Plaintiffs incorporate each of the preceding paragraphs 1-14 as if fully set forth herein.

ANSWER: In response to paragraph 15, Cipla repeats and realleges its responses to the allegations of paragraphs 1–14 of the Complaint as if fully set forth herein.

16. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

ANSWER: Paragraph 16 contains legal conclusions and allegations to which no answer is required. For the limited purpose of this action only, Cipla does not contest subject matter jurisdiction.

17. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery if necessary, this Court has personal jurisdiction over Cipla Limited and Cipla USA, Inc.

ANSWER: Paragraph 17 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla does not contest personal jurisdiction over Cipla Limited and Cipla USA, Inc. in this Court for the limited purpose of this litigation, and denies the remaining allegations of paragraph 17.

18. Cipla Limited and Cipla USA, Inc. are subject to personal jurisdiction in New Jersey because, among other things, Cipla Limited and Cipla USA, Inc. have purposefully availed themselves of the benefits and protections of New Jersey's laws such that those entities would reasonably anticipate being haled into court here. On information and belief, Cipla Limited and Cipla USA, Inc. develop, manufacture, import, market, offer to sell, and/or sell generic drugs throughout the United States, including in the State of New Jersey, and therefore transact business within the State of New Jersey related to Plaintiffs' claims, and/or have engaged in systematic and continuous business contacts within the State of New Jersey.

ANSWER: Paragraph 18 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla admits that Cipla USA, Inc. markets, sells, and/or distributes pharmaceutical drug products, including generic drug products. Cipla admits that Cipla Limited is in the business of manufacturing pharmaceutical drug products, including generic pharmaceutical drug products. Cipla does not contest personal jurisdiction over Cipla USA, Inc. and Cipla Limited in this Court for the limited purpose of this litigation, and denies the remaining allegations of paragraph 18.

19. In addition, this Court has personal jurisdiction over Cipla Limited and Cipla USA, Inc. because, among other things, on information and belief: (1) Cipla USA, Inc. filed Cipla's ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product in the United States, including in New Jersey; and (2) upon approval of Cipla's ANDA, Cipla Limited and Cipla USA, Inc. will directly, or indirectly through subsidiaries, intermediaries, distributors, retailers, or others, market, distribute, offer for sale, sell, and/or import Cipla's ANDA Product in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of Cipla's ANDA Product in New Jersey. *See Acorda Therapeutics Inc. v. Mylan Pharms. Inc*., 817 F.3d 755, 763 (Fed. Cir. 2016). On information and belief, upon approval of Cipla's ANDA, Cipla's ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in New Jersey; prescribed by physicians practicing in New Jersey; dispensed by pharmacies located within New Jersey; and/or used by patients in New Jersey, all of which would have a substantial effect on New Jersey.

ANSWER: Paragraph 19 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla does not contest personal jurisdiction over Cipla Limited and Cipla USA, Inc. in this Court for the limited purpose of this litigation. Cipla admits that Cipla Limited prepared and submitted Cipla's ANDA to the FDA pursuant to 21 U.S.C. § 355(j). Cipla admits that Cipla's ANDA seeks approval from the FDA to engage in the commercial manufacture, use, and/or sale of Cipla's ANDA Product. Cipla will decide whether to market, distribute, offer for sale, sell, and/or import its product in the United States upon FDA approval. Cipla denies the remaining allegations of paragraph 19.

20. This Court has personal jurisdiction over Cipla Limited and Cipla USA, Inc. because those entities (1) engage in patent litigation concerning Cipla's products in this District, and (2) do not contest personal jurisdiction in this District. *See, e.g., Cubist Pharms. LLC v. Cipla USA, Inc. and Cipla Limited*, Civ. No. 19-12920, Dkt. No. 15 (D.N.J. July 2, 2019).

ANSWER: Paragraph 20 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla does not contest personal jurisdiction over Cipla Limited and Cipla USA, Inc. in this Court for the limited purpose of this litigation. Cipla denies the remaining allegations of paragraph 20.

21. Additionally, this Court has personal jurisdiction over Cipla USA, Inc. because, on information and belief, Cipla USA, Inc. maintains its principal place of business in this District.

ANSWER: Paragraph 21 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla admits that Cipla USA, Inc.'s principal place of business is in Warren, New Jersey. Cipla does not contest personal jurisdiction over Cipla USA, Inc. in this Court for the limited purpose of this litigation. Cipla denies the remaining allegations of paragraph 21.

22. Additionally, Cipla has filed an Answer and asserted counterclaims in related actions in this District. *AstraZeneca Pharms. L.P. v. Cipla Ltd.*, Civ. No. 24-7346, Dkt. No. 16 (D.N.J. Sept. 3, 2024); *AstraZeneca Pharms L.P. v. Cipla Ltd.*, Civ. No. 24-8167, Dkt. No. 14 (D.N.J. Oct. 7, 2024). In those Answers, Cipla has consented to personal jurisdiction in this District.

ANSWER: Cipla admits that it filed an Answer and asserted counterclaims in *AstraZeneca Pharms. L.P. v. Cipla Ltd.*, Civ. No. 3:24-7346 (D.N.J.), and *AstraZeneca Pharms L.P. v. Cipla Ltd.*, Civ. No. 3:24-8167 (D.N.J.). Cipla admits that, in those Answers, Cipla did not contest personal jurisdiction in this District for the limited purpose of those litigations only. Cipla denies any remaining allegations of paragraph 22.

23. For the above reasons, it would not be unfair or unreasonable for Cipla Limited and Cipla USA, Inc. to litigate this action in this District, and the Court has personal jurisdiction over those entities here.

ANSWER: Paragraph 23 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla does not contest personal jurisdiction over Cipla Limited and Cipla USA, Inc. in this Court for the limited purpose of this litigation, and denies the remaining allegations of paragraph 23.

Venue

24. Plaintiffs incorporate each of the preceding paragraphs 1-23 as if fully set forth herein.

ANSWER: In response to paragraph 24, Cipla repeats and realleges its responses to the allegations of paragraphs 1–23 of the Complaint as if fully set forth herein.

25. Venue is proper in this District as to Cipla Limited pursuant to 28 U.S.C. § 1391, at least because, on information and belief, Cipla Limited is a foreign corporation that may be sued in any judicial district in which it is subject to the Court's personal jurisdiction.

ANSWER: Paragraph 25 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla does not contest venue over Cipla Limited, Inc. in this Court for the limited purposes of this litigation. Cipla denies the remaining allegations of paragraph 25.

26. Venue is proper in this District as to Cipla USA, Inc. pursuant to 28 U.S.C. § 1400(b), at least because, on information and belief, Cipla USA, Inc. has committed, or will commit, an act of infringement in this District, and has a regular and established place of business in this District. On information and belief, among other things, (1) Cipla filed Cipla's ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product in the United States, including in New Jersey; and (2) upon approval of Cipla's ANDA, Cipla will market, distribute, offer for sale, sell, and/or import Cipla's ANDA Product in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of Cipla's ANDA Product in New Jersey. Further, on information and belief, Cipla USA, Inc. maintains its principal place of business in this District.

ANSWER: Paragraph 26 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla does not contest venue over Cipla USA, Inc. in this Court for the limited purposes of this litigation. Cipla admits that Cipla USA, Inc.'s

principal place of business is in Warren, New Jersey. Cipla admits that Cipla's ANDA seeks approval from the FDA to engage in the commercial manufacture, use, and/or sale, of Cipla's ANDA Product. Cipla will decide whether to market, distribute, offer for sale, sell, and/or import its product in the United States upon FDA approval. Cipla denies the remaining allegations of paragraph 26.

27. Venue is proper in this District as to Cipla Limited and Cipla USA, Inc. because those entities (1) engage in patent litigation concerning Cipla's products in this District, and (2) do not contest that venue is proper in this District. *See, e.g., Cubist Pharms. LLC v. Cipla USA, Inc. and Cipla Limited*, Civ. No. 19-12920, Dkt. No. 15 (D.N.J. July 2, 2019).

ANSWER: Paragraph 27 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla does not contest venue over Cipla Limited and Cipla USA, Inc. in this Court for the limited purpose of this litigation. Cipla denies the remaining allegations of paragraph 27.

28. Additionally, Cipla has filed Answers and asserted counterclaims in related actions in this District. *AstraZeneca Pharms. L.P. v. Cipla Ltd.*, Civ. No. 24-7346, Dkt. No. 16 (D.N.J. Sept. 3, 2024); *AstraZeneca Pharms L.P. v. Cipla Ltd.*, Civ. No. 24-8167, Dkt. No. 14 (D.N.J. Oct. 7, 2024). In those Answers, Cipla has consented to venue in this District.

ANSWER: Cipla admits that it filed an Answer and asserted counterclaims in *AstraZeneca Pharms. L.P. v. Cipla Ltd.*, Civ. No. 24-7346 (D.N.J.), and *AstraZeneca Pharms. L.P. v. Cipla Ltd.*, Civ. No. 24-8167 (D.N.J.). Cipla admits that, in those Answers, Cipla did not contest venue in this District for the limited purpose of those litigations only. Cipla denies any remaining allegations of paragraph 28.

Factual Background

29. LYNPARZA® is approved by FDA for the treatment of certain ovarian, breast, pancreatic, and prostate cancers. The active pharmaceutical ingredient in LYNPARZA® is olaparib, a poly (ADP-ribose) polymerase (PARP) inhibitor.

ANSWER: Cipla admits that LYNPARZA® is approved by the FDA. Cipla admits that the prescribing information for LYNPARZA® dated 11/2023 available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/208558s028lbl.pdf ("Prescribing Information") lists certain types of ovarian, breast, pancreatic, and prostate cancer under the section titled "1 Indications and Usage." Cipla further admits that the Prescribing Information states under the section titled "12.1 Mechanism of Action" that "Olaparib is an inhibitor of poly (ADP-ribose) polymerase (PARP) enzymes . . ." Cipla denies any remaining allegations of paragraph 29.

30. In Cipla's Notice Letter, Cipla states that the subject of Cipla's ANDA is olaparib tablets, 100 mg and 150 mg. In Cipla's Notice Letter, Cipla states that Cipla's ANDA was submitted under 21 U.S.C. § 355(j)(1) and § 355(j)(2)(A) and contends that Cipla's ANDA contains bioavailability and/or bioequivalence studies for Cipla's ANDA Product. On information and belief, Cipla's ANDA Product is a generic version of LYNPARZA®.

ANSWER: Cipla admits that in Cipla's May 2024 Notice Letter, Cipla states that Cipla submitted an ANDA for Olaparib Tablets, 100 mg and 150 mg, to the FDA. Cipla admits that in Cipla's May 2024 Notice Letter, Cipla states that Cipla's ANDA was submitted under 21 U.S.C. § 355(j)(1) and (j)(2)(A). Cipla admits that Cipla's May 2024 Notice Letter states that Cipla's ANDA contains any required bioavailability and/or bioequivalence data from studies on Cipla's ANDA product. Cipla denies the remaining allegations of paragraph 30.

31. The purpose of Cipla's submission of Cipla's ANDA was to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product.

ANSWER: Cipla admits that Cipla submitted Cipla's ANDA to the FDA seeking approval to manufacture, use, and/or sell Cipla's ANDA Product in the United States. Cipla denies the remaining allegations of paragraph 31.

32. In Cipla's Notice Letter, Cipla stated that it had submitted Paragraph IV Certifications to FDA alleging that the '562 patent, the '842 patent, and the '396 patent were invalid, unenforceable, and/or not infringed, and that Cipla is seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '562 patent, the '842 patent, and the '396 patent.

ANSWER: Cipla admits that in Cipla's May 2024 Notice Letter, Cipla states that Cipla's ANDA includes paragraph IV certifications to obtain approval to engage in the commercial manufacture, use, or sale of Olaparib Tablets, 100 mg and 150 mg, before the expiration of the '842 patent, the '396 patent, and the '562 patent. Cipla admits that Cipla's May 2024 Notice Letter states that the patents subject to the paragraph IV certification are alleged to be invalid, and/or not infringed, and/or unenforceable. Cipla denies the remaining allegations of paragraph 32.

33. Following receipt of Cipla's Notice Letter, on February 2, 2024, Plaintiffs filed suit against Cipla alleging that Cipla's ANDA infringes the '562 patent, the '530 patent, the '001 patent, the '842 patent, and the '396 patent. See *AstraZeneca Pharms. L.P. v. Cipla Limited*, Civ. No. 24-7346, Dkt. No. 1. That suit is currently pending in this District.

ANSWER: Cipla denies that Plaintiffs filed suit against Cipla on February 2, 2024. Cipla admits that on June 28, 2024, Plaintiffs filed suit against Cipla alleging that Cipla's ANDA infringes the '562, '530, '001, '842, and '396 patents. Cipla further admits that *AstraZeneca Pharms. L.P. v. Cipla Limited*, Civ No. 3:24-cv-7346 (consolidated into Civ. No. 3:23-cv-796) is currently pending in this District. Cipla denies any remaining allegations of paragraph 33.

34. On information and belief, Cipla has not challenged U.S. Patent No. 8,143,241 or U.S. Patent No. 8,071,579, which are listed in connection with LYNPARZA® in the FDA's Orange Book and expire on August 12, 2027. On information and belief, Cipla has not challenged U.S. Patent No. 7,449,464, which is listed in connection with LYNPARZA® in the FDA's Orange Book and expires on September 8, 2027. On information and belief, following the expiration of those patents, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product immediately and imminently upon FDA approval of Cipla's ANDA.

ANSWER: Paragraph 34 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 34

as phrased and affirmatively states that Cipla will decide whether to market, distribute, offer for sale, sell, and/or import its product in the United States upon FDA approval. Cipla denies the remaining allegations of paragraph 34.

35. On October 30, 2024, the U.S. Patent and Trademark Office issued an Issue Notification for the '810 patent, and indicated that the '810 patent would issue on November 19, 2024.

ANSWER: Cipla admits that the '810 patent issued on November 19, 2024. Cipla denies any remaining allegations of paragraph 35.

36. On November 14, 2024, Plaintiffs notified Cipla's outside counsel of the upcoming issuance of the '810 patent.

ANSWER: Paragraph 36 contains legal conclusions to which no response is required. To the extent a response is required, Cipla admits that Plaintiffs' outside counsel emailed Cipla's outside counsel on November 14, 2024 to explain Plaintiffs purportedly expected the issuance of the '810 patent; Plaintiffs intended to list the '810 patent in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"); and that Plaintiffs expected to file suit alleging Cipla's ANDA product infringes the allowed claims of the '810 patent. Cipla denies the remaining allegations of paragraph 36.

37. On information and belief, Cipla intends to seek approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '810 patent.

ANSWER: Cipla admits that Cipla intends to seek approval from the FDA to engage in the commercial manufacture, use, and/or sale of Cipla's ANDA Product prior to the expiration of the '810 patent. Cipla denies any remaining allegations of paragraph 37.

Count I —[Purported] Infringement of the '810 Patent Under 35 U.S.C. § 271(e)(2)

38. Plaintiffs incorporate each of the preceding paragraphs 1-37 as if fully set forth herein.

ANSWER: In response to paragraph 38, Cipla repeats and realleges its responses to the allegations of paragraphs 1–37 of the Complaint as if fully set forth herein.

39. On November 19, 2024, the USPTO duly and lawfully issued the '810 patent, entitled "Immediate Release Pharmaceutical Formulation of 4-[3-(4-Cyclopropanecarbonyl-Piperazine-1-Carbonyl)-4-Fluoro-Benzyl]-2H-Phthalazin-1-One." A copy of the '810 patent is attached hereto as Exhibit A.

ANSWER: Paragraph 39 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla admits that Exhibit A to the Complaint purports to be a copy of the '810 patent. Cipla admits that the '810 patent is entitled "Immediate Release Pharmaceutical Formulation of 4-[3-(4-Cyclopropanecarbonyl-Piperazine-1-Carbonyl)-4-Fluoro-Benzyl]-2H-Phthalazin-1-One." Cipla admits that the face of the '810 patent lists November 19, 2024 as the issue date. Cipla denies the remaining allegations of paragraph 39.

40. Plaintiff KuDOS Pharmaceuticals Limited is the assignee of the '810 patent. Plaintiffs collectively possess all exclusive rights and interests in the '810 patent.

ANSWER: Paragraph 40 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, according to the face of the '810 patent, KuDOS Pharmaceuticals Limited is listed as the assignee of the '810 patent. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations in paragraph 40 and therefore denies them.

41. The '810 patent claims, inter alia, an immediate-release pharmaceutical composition in the form of a solid dispersion comprising 4-[3-(4-Cyclopropanecarbonyl-Piperazine-1-Carbonyl)-4-Fluoro-Benzyl]-2H-Phthalazin-1-One, known by the international nonproprietary name olaparib, and certain excipients.

ANSWER: Paragraph 41 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla admits that claim 1 of the '810 patent states:

1. An immediate-release pharmaceutical composition in the form of a tablet comprising:

a solid dispersion comprising:

(i) 100 mg to 200 mg of 4-[3-(4-cyclopropanecarbonyl-piperazine-1-carbonyl)-4-fluorobenzyl]-2H-phthalazin-1-one (Compound 1); and

(ii) at least one polymer chosen from copovidone, povidone, hypromellose phthalate, hypromellose acetate succinate, 2-hydroxypropyl-β-cyclodextrin, hypromellose, polymethacrylates, hydroxypropyl cellulose, and cellulose acetate phthalate;

wherein the weight ratio of Compound 1 to the at least one polymer in the solid dispersion is in the range of from 1:1 to 1:9;

wherein the total concentration of Compound 1 in the tablet is in the range of from 10% by weight to 50% by weight; and

wherein the hardness of the tablet is greater than or equal to 25 N.

Cipla denies any remaining allegations of paragraph 41.

42. LYNPARZA® contains olaparib as its active pharmaceutical ingredient.

ANSWER: Cipla admits that according to the Prescribing Information, LYNPARZA® contains olaparib as its active ingredient. Cipla denies any remaining allegations of paragraph 42.

43. LYNPARZA® is covered by claim 1 of the ’810 patent, and the ’810 patent will be listed in connection with LYNPARZA® in the FDA’s Orange Book.

ANSWER: Paragraph 43 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla admits that the ’810 patent is listed in the Orange Book in connection with LYNPARZA®. Cipla denies any remaining allegations of paragraph 43.

44. On information and belief, following the expiration of those patents that Cipla chose not to challenge, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla’s ANDA Product immediately and imminently upon FDA approval of Cipla’s ANDA.

ANSWER: Paragraph 44 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 44 as phrased and affirmatively states that Cipla will decide whether to manufacture, use, offer for

sale, sale, market, distribute, and/or import its product in the United States upon FDA approval. Cipla denies any remaining allegations of paragraph 44.

45. Cipla received notice of the '810 patent at least as of November 14, 2024, when Plaintiffs notified Cipla's outside counsel of the upcoming issuance of the '810 patent.

ANSWER: Paragraph 45 contains legal conclusions and allegations to which no answer is required. To the extent a response is required, Cipla admits that Plaintiffs' outside counsel emailed Cipla's outside counsel on November 14, 2024 to explain Plaintiffs purportedly expected the issuance of the '810 patent; Plaintiffs intended to list the '810 patent in the Orange Book; and that Plaintiffs expected to file suit alleging Cipla's ANDA product infringes the allowed claims of the '810 patent. Cipla denies any remaining allegations of paragraph 45.

46. On information and belief, Cipla intends to seek approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '810 patent.

ANSWER: Cipla admits that Cipla intends to seek approval from the FDA to engage in the commercial manufacture, use, and/or sale, of Cipla's ANDA Product prior to the expiration of the '810 patent. Cipla denies any remaining allegations of paragraph 46.

47. Cipla's submission of Cipla's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '810 patent was an act of infringement of the '810 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

48. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claim 1 of the '810 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

49. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for Cipla's ANDA Product would infringe claim 1 of the '810 patent.

ANSWER: Denied.

50. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '810 patent and knows that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '810 patent after approval of Cipla's ANDA.

ANSWER: Denied.

51. The foregoing actions by Cipla constitute and/or will constitute infringement of the '810 patent, active inducement of infringement of the '810 patent, and contribution to the infringement by others of the '810 patent.

ANSWER: Denied.

52. On information and belief, Cipla has acted with full knowledge of the '810 patent and without a reasonable basis for believing that it would not be liable for the infringing of the '810 patent, actively inducing infringement of the '810 patent, and contributing to the infringement by others of the '810 patent.

ANSWER: Denied.

53. Unless Cipla is enjoined from infringing the '810 patent, actively inducing the infringement of the '810 patent, and contributing to the infringement by others of the '810 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

Count II — [Purported] Declaratory Judgment of Infringement of the '810 Patent

54. Plaintiffs incorporate each of the preceding paragraphs 1-53 as if fully set forth herein.

ANSWER: In response to paragraph 54, Cipla repeats and realleges its responses to the allegations of paragraphs 1–53 of the Complaint as if fully set forth herein.

55. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case or actual controversy between Plaintiffs on the one hand and Cipla on the other regarding infringement and/or invalidity of the '810 patent.

ANSWER: Paragraph 55 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla admits that an actual case or controversy

exists between Plaintiffs and Cipla with respect to the alleged infringement of the '810 patent and the invalidity of the '810 patent. Cipla denies the remaining allegations of paragraph 55.

56. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Cipla's ANDA Product with its proposed labeling, or any other Cipla drug product that is covered by or whose use is covered by the '810 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '810 patent, and that the claims of the '810 patent are valid and enforceable.

ANSWER: Paragraph 56 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 56.

PLAINTIFFS' PRAYER FOR RELIEF

The remainder of the Complaint is a prayer for relief and does not require a response. To the extent any response is required Cipla denies that Plaintiffs are entitled to any remedy or relief sought in paragraphs (1) through (9) on pages 11 through 12 of the Complaint. Should Plaintiffs receive any of their requested relief, no such relief should prevent Cipla from obtaining a Pre-Launch Activities Importation Request from the FDA, or acting under it, in connection with Cipla's ANDA Product. All other allegations in the Complaint not specifically admitted or denied are hereby denied.

SEPARATE DEFENSES

Without prejudice to the denials set forth in its responses to paragraphs 1 through 56 of the Complaint, Cipla alleges the following Separate Defenses to the Complaint. Cipla expressly reserves the right to allege additional defenses as they become known through the course of discovery or other factual investigation. Cipla does not intend to hereby assume the burden of proof with respect to those matters as to which, pursuant to law, Plaintiffs bear the burden of proof.

First Defense
(Invalidity and Ineligibility of the '810 Patent)

Each claim of the '810 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Second Defense
(Noninfringement of the '810 Patent)

Cipla has not, does not, and will not infringe any valid and enforceable claim of the '810 patent. The manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the '810 patent, either literally or under the doctrine of equivalents.

Third Defense
(Estoppel)

Plaintiffs are estopped from asserting infringement by the doctrine of prosecution history estoppel, equitable estoppel, unclean hands, waiver, implied waiver, acquiescence, disclaimer, judicial estoppel, and/or other equitable doctrines.

Fourth Defense
(Failure to State a Claim)

Plaintiffs' Complaint fails to state a claim upon which relief may be granted.

Fifth Defense
(No Exceptional Case)

Cipla's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

Sixth Defense
(Safe Harbor Under 35 U.S.C. §271(e)(1))

Pursuant to 35 U.S.C. § 271(e)(1), Cipla's actions do not constitute infringement.

Seventh Defense
(Ensnarement)

To the extent Plaintiffs claim infringement of one or more claims of the '810 patent under the doctrine of equivalents, Plaintiffs' claims are barred under the ensnarement doctrine, which prohibits Plaintiffs from asserting an infringement theory under the doctrine of equivalents that encompasses or ensnares the prior art.

Eighth Defense
(Lack of Standing)

To the extent that Plaintiffs did not, or do not, hold all substantial rights, title, and interest to the '810 patent, Plaintiffs lack standing to bring, or maintain, this lawsuit in connection with such patent.

Nineth Defense
(Reservation of Defenses)

Defendants reserve all affirmative defenses under Rule 8(c) of the Federal Rules of Civil Procedure, the patent laws of the United States, and any other defenses at law or in equity that may exist now or that may be available in the future, including, but not limited to, those related to the unenforceability of any claim of the '810 patent based on inequitable conduct, as may be determined through discovery and further factual investigation in this actions.

COUNTERCLAIMS

Without admitting the allegations of Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, AstraZeneca AB, KuDOS Pharmaceuticals Limited, and MSD International Business GmbH (collectively, "Plaintiffs" or "Counterclaim Defendants"), other than those expressly admitted herein, Defendants Cipla USA, Inc. and Cipla Limited (collectively, "Cipla" or "Defendants" or "Counterclaim Plaintiffs") bring the following Counterclaims against Plaintiffs/Counterclaim Defendants for declaratory judgment that U.S. Patent No. 12,144,810 (the

"'810 patent") is invalid and/or not infringed by Cipla and the product as described in Cipla's Abbreviated New Drug Application ("ANDA") No. 219410 ("Cipla's ANDA Product")[2]:

The Parties

1. Counterclaim Plaintiff Cipla Limited is an entity organized and existing under the laws of India, having a place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400013, India.

2. Counterclaim Plaintiff Cipla USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 10 Independence Boulevard, Suite 300, Warren, NJ 07059.

3. Upon information and belief, based on the allegations in the Complaint, Counterclaim Defendant AstraZeneca Pharmaceuticals LP is a limited partnership organized and existing under the laws of the State of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803.

4. Upon information and belief, based on the allegations in the Complaint, Counterclaim Defendant AstraZeneca UK Limited is a private company limited by shares organized and existing under the laws of England and Wales, whose registered office is at 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge CB2 0AA, United Kingdom.

[2] Cipla has also filed counterclaims for non-infringement and invalidity for U.S. Patent Nos. 8,475,842, 8,859,562, 11,633,396, 11,975,001, and 12,048,695. *See, e.g.*, Cipla's Answer, Separate Defenses, and Counterclaims, *AstraZeneca Pharms. L.P. v. Cipla Limited*, No. 23-cv-796 (D.N.J. Sept. 3, 2024), ECF Nos. 116, 133; Cipla's Answer, Separate Defenses, and Counterclaims, *AstraZeneca Pharms. L.P. v. Cipla Limited*, No. 24-cv-7346 (D.N.J. Sept. 3, 2024), ECF No. 16; Cipla's Answer, Separate Defenses, and Counterclaims, *AstraZeneca Pharms. L.P. v. Cipla Limited*, No. 24-cv-8167 (D.N.J. Oct. 7, 2024), ECF No. 14.

5. Upon information and belief, based on the allegations in the Complaint, Counterclaim Defendant AstraZeneca AB is a limited company organized and existing under the laws of Sweden, whose registered office is at SE-151 85, Södertälje, Sweden.

6. Upon information and belief, based on the allegations in the Complaint, Counterclaim Defendant KuDOS Pharmaceuticals Limited is a private company limited by shares organized and existing under the laws of England and Wales, whose registered office is at 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge CB2 0AA, United Kingdom.

7. Upon information and belief, based on the allegations in the Complaint, Counterclaim Defendant MSD International Business GmbH is a company with limited liability organized and existing under the laws of Switzerland, whose registered office is at Tribschenstrasse, 60, 6005 Lucerne, Switzerland.

8. Upon information and belief, and based on the U.S. Food and Drug Administration's ("FDA's") electronic *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") Counterclaim Defendant AstraZeneca Pharmaceuticals LP is the holder of New Drug Application No. 208558.

9. Upon information and belief, Counterclaim Defendants currently promote and market LYNPARZA® in the United States.

Jurisdiction and Venue

10. This court has subject matter jurisdiction over the Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 2201, 2202, 1331, 1338(a), and 1367, based on an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants arising under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*

11. This Court has personal jurisdiction over Counterclaim Defendants because Counterclaim Defendants have availed themselves of the rights and privileges and subjected themselves to the jurisdiction of this forum by suing Cipla in this judicial district.

12. Venue is proper in this district for the purposes of these Counterclaims because Counterclaim Defendants filed the present action in this district.

13. On or about November 20, 2024, Counterclaim Defendants filed a civil action in this judicial district against Cipla alleging infringement of the '810 patent. There is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding Cipla and Cipla's ANDA Product's non-infringement of the '810 patent and the invalidity of the '810 patent.

Lynparza® (olaparib)

14. AstraZeneca Pharmaceuticals LP purports to be the holder of approved New Drug Application ("NDA") No. 208558, under which the United States Food and Drug Administration ("FDA") granted approval for Olaparib tablets 100 mg and 150 mg marketed in the United States under the trade name Lynparza®.

15. At the time the Complaint was filed, the '810 patent was not listed in the Orange Book in connection with LYNPARZA®. On or around December 10, 2024, the '810 patent was listed in the Orange Book in association with LYNPARZA®.

The '810 Patent

16. Based on the allegations in the Complaint and Exhibit A attached to the Complaint, the '810 patent, entitled "IMMEDIATE RELEASE PHARMACEUTICAL FORMULATION OF 4-[3-(4-CYCLOPROPANECARBONYL-PIPERAZINE-1-CARBONYL)-4-FLUORO-

BENZYL]-2H-PHTHALAZIN-1-ONE" was issued on November 19, 2024. The face of the patent lists KuDOS Pharmaceuticals Limited as the assignee.

17. On information and belief, Counterclaim-Defendants allege that certain Counterclaim-Defendants have the right to enforce the '810 patent.

18. By listing the '810 patent in the Orange Book, AstraZeneca Pharmaceuticals LP maintains that an infringement suit could be asserted reasonably against an ANDA applicant, including Cipla, that attempts to seek approval for, and market, a generic version of Lynparza® before the expiration of the '810 patent.

19. On or about November 20, 2024, Counterclaim Defendants brought this present action alleging infringement of the '810 patent.

Cipla's ANDA Product

20. Cipla filed ANDA No. 219410, which seeks approval from FDA to engage in the commercial manufacture, use, and/or sale, of the product described in Cipla's ANDA.

First Counterclaim
(Declaratory Judgment of Noninfringement of the '810 Patent)

21. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 20 of the Counterclaims as if fully set forth herein.

22. Counterclaim Defendants have accused Cipla of infringing the '810 patent.

23. Cipla denies infringement of the '810 patent and alleges that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe, induce infringement of or contribute to infringement of, either literally or under the doctrine of equivalents, any valid and enforceable claims of the '810 patent.

24. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding infringement of any valid and enforceable claim of the ’810 patent.

25. Cipla is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Cipla’s ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the ’810 patent.

Second Counterclaim
(Declaratory Judgment of Invalidity of the ’810 Patent)

26. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 25 of the Counterclaims as if fully set forth herein.

27. The claims of the ’810 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

28. Each claim of the ’810 patent is invalid and/or not infringed by Cipla’s ANDA Product.

29. Upon information and belief, Cipla believes that Counterclaim Defendants will continue to assert that Cipla’s ANDA Product is infringing the claims of the ’810 patent and will continue to try to interfere with Cipla’s business with respect to Cipla’s ANDA Product.

30. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of

sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of all claims of the ’810 patent.

31. Cipla is entitled to a judicial declaration that all claims of the ’810 patent are invalid for failure to satisfy one or more of the requirements of Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Request for Relief

WHEREFORE, Cipla requests that this Court enter judgment against Counterclaim Defendants:

A. Declaring that the manufacture, use, sale, offer for sale, and/or importation of Cipla’s ANDA Product does not and will not directly or indirectly infringe any claim of the ’810 patent, either literally or under the doctrine of equivalents;

B. Declaring that the claims of the ’810 patent are invalid and/or unenforceable;

C. Ordering that Counterclaim Defendants’ Complaint be dismissed with prejudice and judgment entered in favor of Cipla;

D. Preliminarily and permanently enjoining Counterclaim Defendants, its employees and agents, and any other person acting in concert with any of them, from asserting or threatening to assert any alleged rights arising under the ’810 patent against Cipla or any person or entity working in concert with Cipla;

E. Awarding Cipla its costs and expenses incurred in this action;

F. Declaring that this is an exceptional case in favor of Cipla and awarding Cipla its reasonable attorneys’ fees pursuant to 35 U.S.C. § 285;

G. Awarding Cipla such other and further relief as the Court may deem proper.

DATED: January 17, 2025

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LOCAL CIVIL RULE 11.2 CERTIFICATION

Under Local Civil Rule 11.2, the undersigned counsel for Cipla Limited and Cipla USA, Inc. hereby certifies that, to the best of my knowledge, the following actions involve some of the same patents as the Patents-in-Suit:

- *AstraZeneca Pharmaceuticals LP et al. v. Cipla Ltd., et al.*, No. 3:24-cv-10628, pending before the United States District court for the District of New Jersey, involves the '810 patent;
- *AstraZeneca Pharmaceuticals LP et al. v. Natco Pharma Ltd. et al.*, No. 3:24-cv-10624, pending before the United States District Court for the District of New Jersey, involves the '810 patent;
- *AstraZeneca Pharmaceuticals LP et al. v. Sandoz Inc.*, No. 3:24-cv-10627, pending before the United States District Court for the District of New Jersey, involves the '810 patent;
- *AstraZeneca Pharmaceuticals LP et al. v. Zydus Pharmaceuticals (USA) Inc. et al.*, No. 3:24-cv-10629, pending before the United States District Court for the District of New Jersey, involves the '810 patent.

I certify under penalty of perjury that the foregoing is true and correct.

Dated: January 17, 2024

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, the undersigned counsel for Cipla Limited and Cipla USA, Inc. hereby certifies that this action seeks declaratory judgement and therefore this action is not appropriate for compulsory arbitration.

Dated: January 17, 2024

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IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, ASTRAZENECA AB, KUDOS PHARMACEUTICALS LIMITED, THE UNIVERSITY OF SHEFFIELD, and MSD INTERNATIONAL BUSINESS GMBH, Plaintiffs, v. NATCO PHARMA LIMITED, NATCO PHARMA INC., SANDOZ INC., CIPLA LIMITED, CIPLA USA, INC., ZYDUS PHARMACEUTICALS (USA) INC. and ZYDUS LIFESCIENCES LIMITED, Defendants.	Civil Action No. 3:23-796 (RK) (TJB) (Consolidated) **CERTIFICATE OF SERVICE** ***Document Electronically Filed***

LOLY G. TOR, of full age, hereby certifies as follows:

1. I am an attorney-at-law of the State of New Jersey and admitted to practice before the United States District Court for the District of New Jersey and partner with the law firm of K&L Gates LLP, attorneys for Defendants/Counterclaim-Plaintiffs Cipla Limited and Cipla USA, Inc.

2. I hereby certify that on the date indicated below, I caused a copy of Defendants/Counterclaim-Plaintiffs Cipla Limited and Cipla USA, Inc.'s Answer, Separate Defenses, and Counterclaims, Fed. R. Civ. P. 7.1 Corporate Disclosure Statement, and this certificate of service to be served upon all counsel of record by CM/ECF.

3. I certify under penalty of perjury that the foregoing is true and correct.

Dated: January 17, 2024

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